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ORIGINAL PAPER

Design and Development of a Clinical Risk Management Tool Using Radio Frequency Identification (RFID)

Faramarz Pourasghar[1], Jafar Sadegh Tabrizi[2], and Khadijeh Yarifard[3]

[1]Road Traffic Injury Research Center and Department of Medical Informatics, School of Management and Medical Informatics, Tabriz University of Medical Sciences, Tabriz, Iran
[2]Health Services Management Research Center, Department of Health Services Management, School of Health management and Medical Informatics, Tabriz University of Medical Sciences, Tabriz, Iran
[3]Student research committee and Department of Health Services Management, School of Health Management and Medical Informatics, Tabriz University of Medical Sciences, Tabriz, Iran

Corresponding author: Khadijeh Yarifard, Fax: 98-041-33352291, Tel:98-041-33361366. E-mail:Yarifardkh@yahoo.com

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ABSTRACT

Background: Patient safety is one of the most important elements of quality of healthcare. It means preventing any harm to the patients during medical care process. **Objective:** This paper introduces a cost-effective tool in which the Radio Frequency Identification (RFID) technology is used to identify medical errors in hospital. **Methods:** The proposed clinical error management system (CEMS) is consisted of a reader device, a transfer/receiver device, a database and managing software. The reader device works using radio waves and is wireless. The reader sends and receives data to/from the database via the transfer/receiver device which is connected to the computer via USB port. The database contains data about patients' medication orders. **Results:** The CEMS has the ability to identify the clinical errors before they occur and then warns the care-giver with voice and visual messages to prevent the error. This device reduces the errors and thus improves the patient safety. **Conclusion:** A new tool including software and hardware was developed in this study. Application of this tool in clinical settings can help the nurses prevent medical errors. It can also be a useful tool for clinical risk management. Using this device can improve the patient safety to a considerable extent and thus improve the quality of healthcare.

Key words: Clinical Risk Management; Patient Safety; Radio Frequency Identification (RFID).

1. INTRODUCTION

Since the release of the Institute of Medicine (IOM) report "To Err is Human" the patient safety has become a focal point and an important clinical issue. Medical errors not only have adverse effect on the individual's health, but also results in increased service costs and waste resources (1, 2). On the other hand, patient safety is one of the main elements of quality healthcare and is defined as avoiding any harm to the patients during the care delivery (3). Errors can occur in different stages of care delivery (1). Medical errors, due to their high prevalence, are one of the most serious problems of health care systems. It is estimated that one of every 10 hospitalized patients in developing countries is faced with harm or injury resulted from medical errors (4). The Institute of Medicine America reported in 1999 that more than one million medical errors occur in the United States every year of which 98000 result in death (5). The medical errors and adverse events are the 8^{th} cause of death (1, 6). It stands higher than traffic accidents, breast cancer and AIDS (1). After the report many countries emphasized on risk management and patient safety which the World Health Organization (WHO) also affirmed it (7).

Various technologies have been used to prevent and reduce medical errors. The Radio Frequency Identification (RFID) has some advantages over other measures (5). It has high capacity to store data safely and the risk of damage to the RFID tags is very little compared to bar code labels. The RFID reader can read data several times faster than bar code reader (5, 8). A system based on RFID technology is consisted of three parts: tag, RFID reader, and a database for storing data. The tag is the identification label and is attached to people or things (9). The tags, based on their function, are categorized in three types of active, passive and semi-passive. Passive tags just reflect the radio signals of the reader and have not power supply. Therefore they are used in short distances (10cm- 4.5 m). Active tags have power supply, therefor are able to send radio signals and are used in distances up to 90 meters. Semi-passive tags have power supply too but send the radio signals only when they are in effective environment of the detector. The reader is a hardware that transfers the data between the tag and the software (database) and vice versa. The readers are also classified as active and passive. The active readers send signals and receive replies from tags and the passive readers only receive radio signals from active tags. Readers are classified in three types based on the supported distance of low frequency, high frequency, and ultra-high frequency. Readers are used in three forms of fixed, hand held, and PC card reader (10).

The RFID is among top ten information technologies (11) and is used in aerospace, military, library, pharmaceuticals, transportation and other industries (9, 12). In recent years its application is expanded to the healthcare. Examples of its application in healthcare are tracing medical equipment, patient entrance and exit control, assuring right drug administration to right patient, and preventing the use of wrong medication (2, 13). It can also be used for stock management via online access to inventory of stocks, blood bank, and expensive drugs. Use of RFID in hospital would have benefits for managers, staff and the patients. Managers would benefit from standardization and simplification of tasks and improving quality of documentation. Healthcare staff would benefit from quick and easy access to patient medical data (14). And the patients would benefit from reduced medical errors. RFID can also help reduce the errors in drug distribution and administration as well as saving the time of staff in routine activities (13), reducing the time of clinical interventions, reducing staff workload (15, 16), improving treatment process, cost saving, improving drug provision, and increasing patient satisfaction. This paper describes the design and development of a cost-effective clinical risk management tool using the RFID technology.

2. METHODS

The software and hardware developed in this study is part of model designed for risk management and patient safety in hospital. The model is consisted intelligent software connected to a database for physician order entry, the RFID reader, the transfer/receiver, and the tags. RFID tags are used for identifying patients (embedded in bracelet), nurses (attached to the nurses' ID cards) and drugs (attached to the drugs). For identifying other medical services a tag is attached to medical device (for instance sphygmomanometry). After the patient is admitted to the ward, his/her personal information and the physician orders are entered into the CEMS and a unique identification code is assigned to the patient. Then the code is saved on RFID tag embedded in bracelet. Similar process is done for the nurses, drugs and devices.

Each time the nurse administer physician's order, she introduces herself to the CEMS by holding the reader over her ID card. Then the reader is drawn over the patient bracelet and then drug or medical device. If the drug or device dis-matches with the physician order recorded in the database, the CEMS detects the imminent error and the reader alerts the nurse. The alert is in form of a voice signal and a red light on the reader. All the transactions are saved automatically on a log file in the CEMS for future analysis.

The available readers in the market were not appropriate to the study purpose, therefore we decided to design a specific one. We needed a reader that in addition to reading the data from the tags, it can also show error messages as voice and visual alarms. Details of the software and hardware developed in this study are as follow:

2.1. Reader

The reader developed in this study is a hand held device. It is designed to read the tags from a 10 centimeters distance. This distance is considered to prevent the error of reading the nearby tags by accident. It is also designed in a way to prevent reading more than one tag at a time; therefore if, after reading a tag, the reader is unintentionally placed near to other tags, the data of new tag will not replace the previous one. The reader works on 400 MHz frequency band and can exchange data with the receiver on 20 meter distance. Its dimension is 11*5.5*3 centimeter and weighs 150 g. There are three push-buttons on the reader and ON/OFF light. Three color lights (function lights) are located vertically on the upper surface. There is a 2 cm external antenna on the top of the device. If a problem occurs when the reader sends data (due to exceeding distance limit between reader and receiver or due to existence of noise in the environment) or if the tag is damaged and not readable, the reader resets after 5 seconds and the data of the last tag will be cleared automatically from device memory. In this case the reader produces a voice alarm to inform the user and the user must re-read the last tag.

Push-buttons: a) Green button: After reading tag, pushing this button sends the data to the server.; b) yellow button: When a tag is read mistakenly, pushing this button clears its data from device memory and nurse can try reading the right tag. Also when the nurse's job with the patient is done, pushing this button clears the patient's data from the reader and the system becomes ready for the next patient. In case of alarms (due to error), before doing the next task the user must push the yellow button to clear data and stop alarm; c) Red button: It is used for registering new drugs. After attaching RFID tag to new drugs, pushing this button and then reading the tag will register the drug in the database.

The lights: a) green light: If the process of identify nurse, patient and drug is done correctly this light turns on.; b) yellow light: When the user, patient, and the care are right but there is a negligible error (for instance delay in providing a non-vital service like measuring body temperature), this light turns on. Then the user decides whether to proceed or not; c) red light: If there is an error in patient identification or service identification this light turns on. For example when the Heparin is prescribed for a particular patient and the nurse mistakenly is going to inject Atropine instead of it, the red light turns on and alerts the nurse to abort the task.

Besides the color lights, the system uses voice messages to alert the user about the task. When everything is correct and the green light is on, a single beep is played. When the yellow light turns on, two beeps are played, and when the red light turns on, a continuous beep is played.

Transfer/Receiver: The reader device reads RFID tags and sends data as a 37 character string to the transfer/ receiver device and the receiver delivers the data into the main software. After the software analyzes the data, the receiver sends feedback (approved or unapproved signal) to the reader as a 3 character string. The receiver is 10*6*2 cm and weighs 100 g. It has a 4cm antenna and a light indicator to show data transfer. This device is connected to the PC through a USB port.

Software and Database: CEMS (Clinical Error Management System) is developed using Visual Basic programming language. The Microsoft Access 2007 was used as database management system. All transactions are recorded in database for further analysis. CEMS logic is presented as flowchart in Figure 1.

PC requirements: One of the main purposes of the project was developing a CEMS that works on any computer with minimum capabilities. The software is developed in .NET environment and can run on any PC with Microsoft Windows operating system. The PC must have one free USB port to connect the receiver.

2.2. System logic

Data transfer: Each RFID tag contains a 12 character code. After the reader has read 3 tags consecutively (nurse tag, patient tag, bed /drug tag), sends the data as a string of 37 characters to the receiver. It is quite often that more than one nurse deliver services to the patients at the same time, therefore more than one reader would send data to the system and we need to identify readers. The 37^{th} character of the string is dedicated to the reader device's ID. The sequence of the characters in the code that the reader sends is as follow: From left to right it contains the reader ID (1 character), the user's tag (12 characters), the patient's tag (12 characters), and the drug's or service's tag (12 characters).

The sequence is important. The code of the drug or service is the last 12 characters of the code and is variable. So until the delivering of services to a particular patient are not finished yet, just reading the tag of nest drug or service is enough and there is no need to repeat the identification of the nurse and patient. After the nurse's work with one patient is over, she pushes the yellow button to clear the data of the patient and drug/service (last 24 characters). The CEMS receives the data, analyzes it and responds to the reader. Maximum time allocated for transaction between reader and main server is 2 seconds. During this time period the CEMS should inform the nurse. Based on the response, one of the reader's colored lights turns on and the relevant voice message is played simultaneously to inform the user.

2.3. The software

The software is consisted of several sections. The user interface includes a section for registering users (nurses), a section for registering patient information, a section for entering physician orders, and a reports section. At the status bar, the transaction between readers and receiver can be seen graphically. Data analysis is done in the background. Results of the analysis are available for the users as charts. After the admission of a new patient, his/her demographical information and also clinical information are registered in the system. Then the physician orders for the patient, including medication name, dosage and frequency are entered to CEMS . To facilitate the data entry of physician order when the physician repeats the previous orders, the order is copied with single click. CEMS log every error occurs during drug administration and can be reported. The log record contains the error type, the user ID, the patient ID, and the ward information including the number of patients at

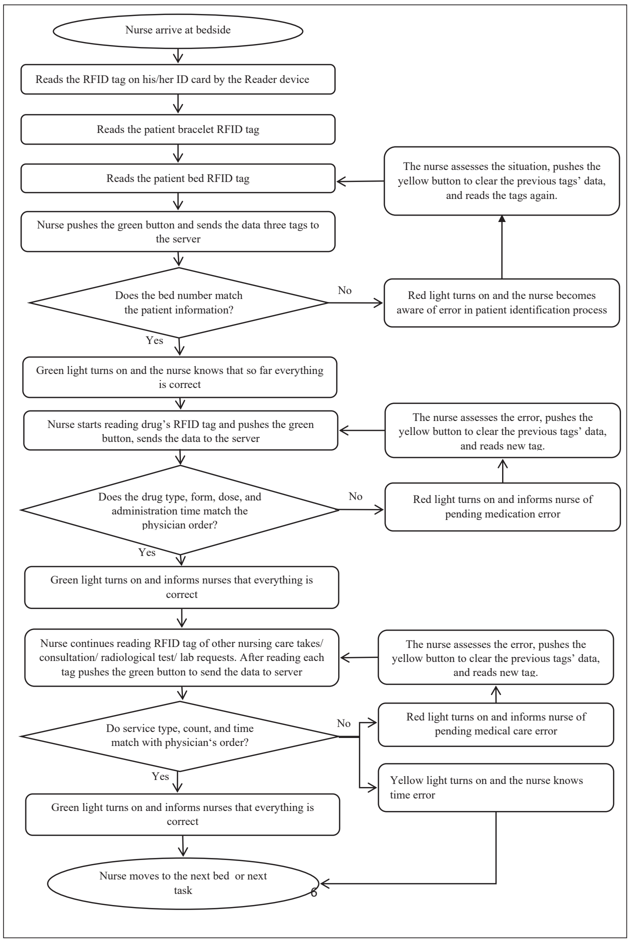

Figure 1. Clinical Error Management System flowchart

the ward when error happened (to evaluate workload of nurses), working shift, time, and the number of nurses at that particular time at the ward. An example of medication error report is presented in Figure 2.

3. RESULTS

We developed a tool to identify and prevent medical errors in the hospital and other care setting. The CEMS is affordable, simple and user-friendly. The reader device developed in this project is hand held and produces graphical and voice alerts to inform the user.

To ensure the performance of the CEMS before piloting it in the hospital, we used clinical scenarios in which medical errors inward happen. These scenarios included errors regarding administrating medication to wrong patient, wrong drug, wrong dosage, and wrong time for medication administration. The scenarios also included medication and non-medication orders in different work shifts and varying doses. The CEMS's performance was satisfying. Data transfer was good. The reader correctly read the tags of users, patients, and drugs/services. Performance of the color lights and the push buttons was correct. After all, the CEMS is ready for pilot implementation in hospital.

4. DISCUSSION

A novel clinical risk management tool - CEMS- was developed in this study which identifies and prevents the errors in medical care giving process. Application of this tool in hospitals would lead to increased patient safety and improved quality of services. The system's most important features are as follow (Figures 3 and 4):

Data entry: Documentation is one of the main activities of healthcare personnel and takes a lot of their time. To simplify the data entry in the risk management system developed in this study, we used automatic copying of the orders. All drugs with their different forms, doses, administration route, and frequency have already been saved in the CEMS and the user simply selects the intended one by clicking the mouse on it. It is possible to change the order whenever the user wants and then the database will be updated immediately. If the user does not change the orders for a particular patient, the orders will be repeated automatically and valid until the patient is discharged or the order is modified.

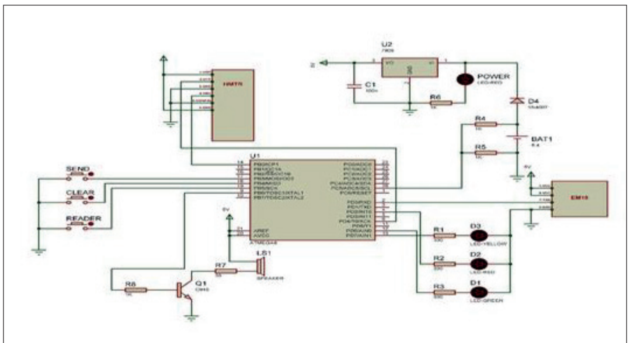

Figure 3. Schematic of the reader device.

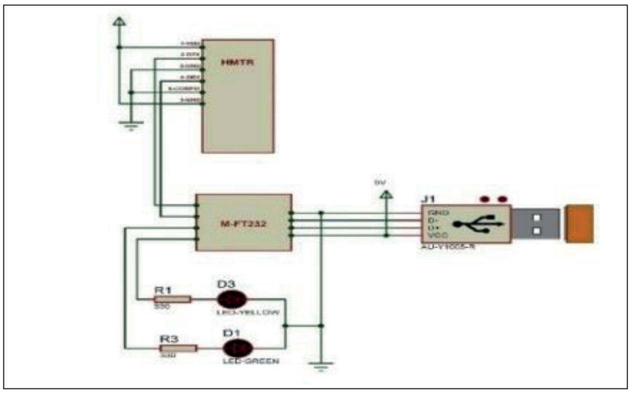

Figure 4. Schematic of the receiver/transfer device

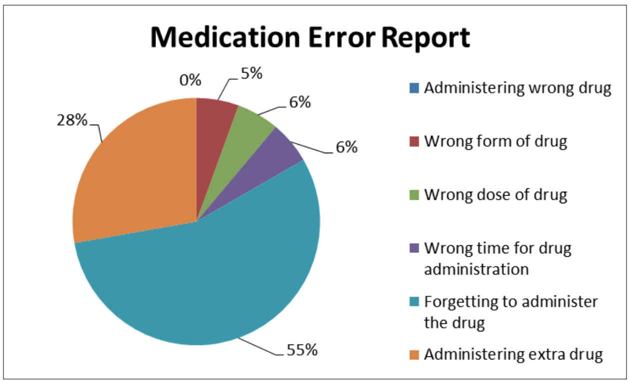

Figure 2. Medication error report based on the error type. Most of the errors had occurred by forgetting to administer the drug and administering extra doses of the drug.

All transactions of the CEMS are permanently recorded in database for future analysis. A complete list of possible errors exists in the CEMS including patient identification error, medication errors (6 possible errors), and service errors (14 possible errors including nursing care, consultation, lab tests, radiology test request errors). All of these errors can be reported separately based on the user's need. The reports can be presented in tables or graphical charts. The error reports are: administering wrong drug, wrong form of drug, wrong dose of drug, wrong time of drug administration, forgetting to administer the drug, administering extra drug, forgetting nursing care, wrong time for nursing care, wrong nursing care, forgetting to have consultation, wrong time of consultation, wrong consultation, forgetting lab test, wrong time of lab test, wrong lab test, repeated lab test, forgetting graph, wrong time to take radiological test, wrong radiological test, repeated radiological test, and the report of patient identification (wrong patient). Furthermore, some other reports are available by the CEMS that may be helpful for ward management. These reports include the report of errors divided by work shifts, the report of errors based on the number of patients of the ward, based on the number of the nurses, nurses' education, nurses' work experience years, and also based on disease type.

Portability: Nurses use several medical devices in their routine work and thus we designed the reader device to be light weight and can be handled easily.

Multi-purpose design: Available readers at the market only can read the tags' data and send it to the database. While we needed a reader that can communicate with the CEMS in a two-way manner. Features of an appropriate reader for the project purpose were:

The reader must have a memory to save the information of 3 consecutive tags and send them in one transaction. The aim of this was to reduce the number of transactions and then to speed up the works. The reader must ensure the user about the completed data transfer. Hospitals are equipped with several medical devices and each one produces electromagnetic noise. Because of this, the reader developed in this study waits to receive confirmation from sever after sending the tag's data. During this time interval, which is supposed to be less than 1 second, the reader becomes temporarily inactive and cannot read a new tag. If the predetermined time passed and no reply received by the reader, the reader activates the yellow button and plays a beep to inform the user about the incomplete data transfer. The user pushes the yellow button, the data about last tag is cleared from the memory, and the reader becomes ready for reading the tag again.

Color lights: Since visual alarms can help individuals to prevent errors, we used the color LED lights on the reader. The lights are green, yellow and red, just similar to the traffic lights. All users are familiar with the concept of these colors in daily life. The green light lets the user to proceed, the yellow one warns the user to re-assess the situation, and the red light stops the user from doing the error.

Voice messages: We used the voice messages alongside the visual alarms to attract the attention of the user and thus to help to reduce the errors.

More than one reader: Usually more than one nurse is giving care to the patients at the same time at the same ward. Then we needed a CEMS by which more than one reader can work without conflict. To this purpose a unique code was assigned to each reader and the reader sends its code with the tags' data.

Power supply: The reader developed in this study is an active one and has a rechargeable battery. The battery can support the device for almost two hours which is usually sufficient for a nurse to do his/her tasks. Furthermore they are provided with charger at the nursing station whenever it is needed.

Affordability: The tool is developed by minimum cost and is considerably cheaper compared to the commercial tool. It can be developed in a short time and its parts can be replaced easily.

User-friendliness: Any unnecessary complexity is avoided in system design and users can easily handle it with daily routines. The push buttons are located on top of the reader for convenience Low weight and comfortable size of the reader allows carrying and using it by one hand.

Safety: The reader is made of compact plastic and if it falls accidentally it will not be harmed. It is designed to read the tags on a 10 cm distance to prevent interference. It does not read more than one tag at a time to prevent unintentional error. The tool works within standard radio frequency band for medical devices which has no harm for the user or the patients.

Messages are easy to understand: The user is provided with the visual and voice messages to help understanding the situation in noisy and crowded environments. Both voice and visual messages are simple and easy to understand.

Tool limitations: The clinical risk management tool developed in this study has some limitations. The reader device has not a display screen. A display on the reader, alongside the voice and color lights, could help the user know his/her work's feedback. The CEMS can transfer data with the reader in a 20 m range. This helps the confidentiality of the data and prevents any potential hacking. But on the other hand it restricts the use of the CEMS in large hospital wards. Finally, the data transfer between the reader and the software is not encrypted. Encryption not only can help the confidentiality of the patient data, but also prevents any changes to the data during transmission.

5. CONCLUSION

We used the RFID technology to develop a clinical error management system which identifies and prevents medical errors before they occur. The software and hardware developed in this study is applicable in clinical settings. It is simple, user friendly and easy to understand. The CEMS provides the user with detailed reports about the errors. It has also some managerial reports to help the management of the ward in reducing the errors. Using this tool would improve patient safety and the quality of healthcare services.

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